

Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

13 418



2 - LABEL SAMPLE

000001

DUCT LABELING

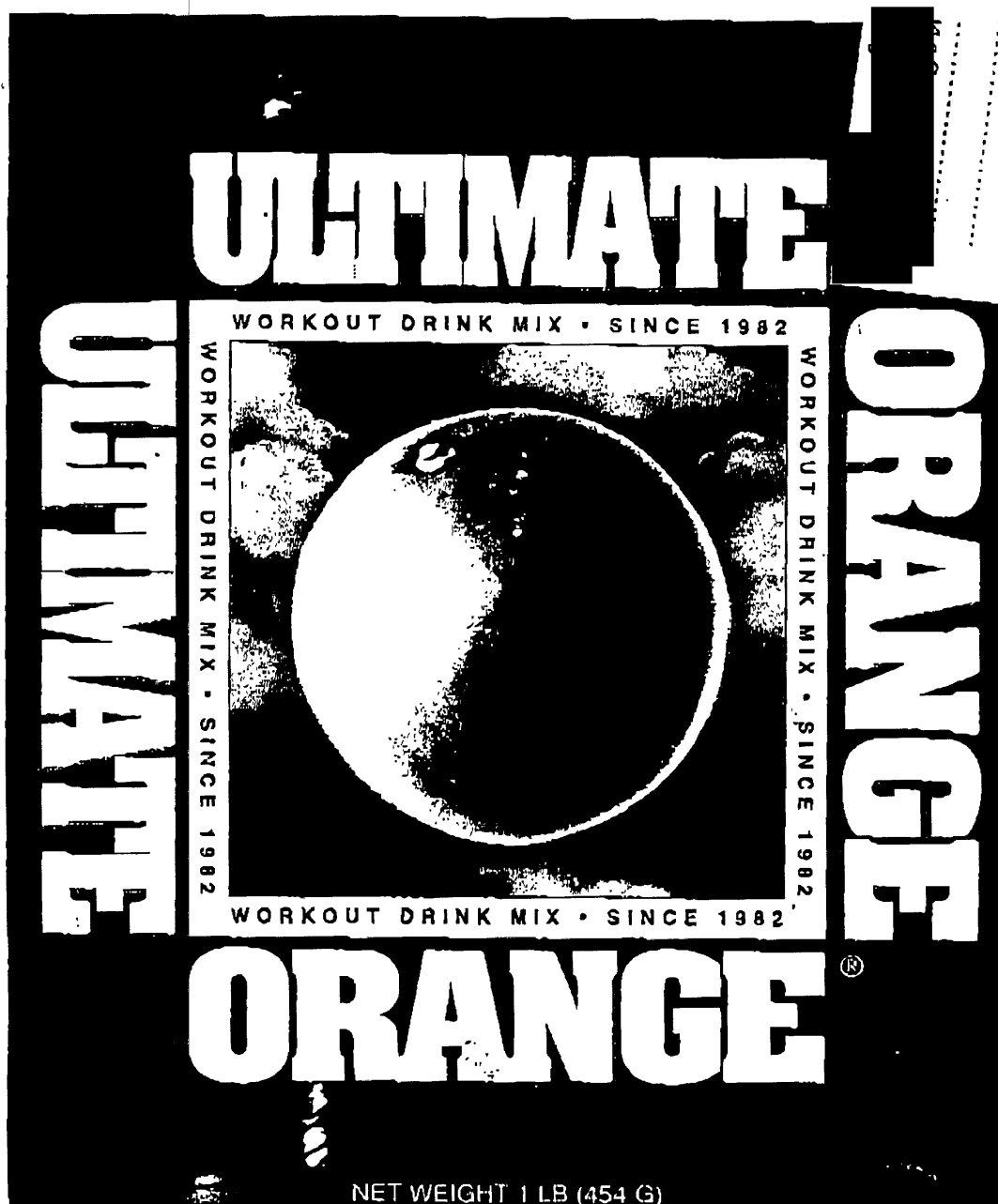
FAX NO. 03

P. 02

59884

7/14/99 ~~8/24/99~~

CENTER PANEL



RECEIVED
CLINICAL RESEARCH
& REVIEW/OSN HFS-472

99 JUL 27 AM 1:40

000002

ARM 5 13418

Actual Consumer Label

PRODUCT LABELING

59884
7-14-99 JCBUSSEY

LEFT PANEL

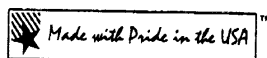
Nutrition Facts		
Serving Size 1 level scoops (28.4g)		
Servings Per Container 16		
Amount Per Serving		
Calories 101		Calories from Fat 9
		% Daily Value*
Total Fat 1g		1.5%
Saturated Fat .4g		2%
Cholesterol 0mg		0%
Sodium 75mg		3%
Potassium 220mg		6.4%
Total Carbohydrates 16g		5.3%
Dietary Fiber .5g		2%
Sugars less than .4g		
Protein 7g		14%
Vitamin A 50% • Vitamin C 80%		
Vitamin D 15% • Vitamin E 80%		
Thiamin (B ₁) 50% • Riboflavin (B ₂) 50%		
Niacin 50% • Vitamin B ₆ 400%		
Folic acid 50% • Vitamin B ₁₂ 80%		
Biotin 50% • Pantothenic Acid 400%		
Calcium 20% • Iron 20%		
Phosphorous 15% • Iodine 50%		
Magnesium 30% • Zinc 50%		
Selenium 29% • Copper 15%		
Manganese 100% • Chromium 21%		
Molybdenum 40%		
* Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs.		
	Calones	2,000 2,500
Total Fat	Less than	65g 80g
Sat Fat	Less than	20g 25g
Cholesterol	Less than	300mg 300mg
Sodium	Less than	2,400mg 2,400mg
Total Carbohydrates		300g 375g
Dietary Fiber		25g 30g
Calories per gram		
Fat 9 • Carbohydrate 4 • Protein 4		

This product is packed by weight and not volume. Some settling of the contents will have occurred during transportation.

INGREDIENTS

QUADRACARB [4 stage release carbohydrate from branching chain glucose polymers from amylopectins, high glycemic index maltose with dextrose, plus low glycemic index fructose], **LACTOPRO** [high biological value, low lactose Lactoglobulin, Lactalbumin, Lactoferrin and immunoglobulin protein fractions from whey protein concentrate], **BIOVITE** [bioactive vitamin-mineral blend of potassium phosphate, calcium carbonate, magnesium oxide, zinc gluconate, ferrous fumarate, boron tri-citrate-aspartate-glycinate, potassium iodide, retinyl palmitate, pyridoxine HCl, niacin, riboflavin, thiamine, chromium arginate, biotin, ergocalciferol, cyanocobalamin, betacarotene, ferrous succinate, chromium picolinate], citric acid, **ULTIMATE ORANGE HERBAL CONCENTRATE** [a proprietary herbal powder blend from Ma Huang, Guarana Seed, Green Tea, Siberian Ginseng, and Bioflavanoids from orange peel], Structured Lipid Complex [medium chain triglycerides with omega-3 fatty acids], Xylitol, natural flavors, lecithin, cellulose gum, food coloring.

WARNING: EACH 28.4 GRAM SERVING CONTAINS 20 MG OF EPHEDRA ALKALOIDS FROM A STANDARDIZED EXTRACT OF THE NATURAL MA HUANG HERB. MAXIMUM RECOMMENDED DOSAGE OF EPHEDRA ALKALOIDS IS NO MORE THAN 60 MG IN A 24 HOUR PERIOD FOR NOT MORE THAN 12 WEEKS.



Store in a cool dry place out of direct sunlight. Like all naturally derived products, appearance may differ slightly from one batch to another. A free measuring scoop is included in this container.

A product from

NEXT NUTRITION®
putting science to work...
for you!

P.O. Box 2469 • Carlsbad, CA 92018



59884 6/11/99 JCBUSSEY

000003

UCT LABELING

59884
7/14/99 LUBUSSEY

RIGHT PANEL

Have you experienced **Ultimate Orange®?**

Like no other drink, pill or capsule you can find today, **Ultimate Orange** has been helping serious athletes maximize workout results for over 17 years. With a few shakes of a water bottle or stirs of a spoon, you can experience a precise ratio of energy-packed nutrients for maximum intensity and focus. But do remember, **Ultimate Orange** is not for everybody. Any doubts, see the important notice below.



WHEN TO DRINK **ULTIMATE ORANGE**

Before exercise: Drink one serving for body weight 15-25 minutes prior to exercise.

During exercise: Take sips between sets or every 5-10 minutes throughout your workout. Avoid gulps all at once.



HOW MUCH **ULTIMATE ORANGE** TO DRINK

Follow the table below as guideline of useage amounts versus body weight. Each person has a unique metabolism that may require a slightly smaller or larger serving size for preferred effects.

Bodyweight	lbs	132	154	176	198	220
	kgs	60	70	80	90	100
Number of scoops		1/2	1/2-3/4	1	1-1 1/2	1 1/2

MIXING INSTRUCTIONS



Place 1 level scoop in a glass, add 8 oz. water, stir and drink. **Ultimate Orange** mixes quickly with a few stirs of a spoon. There is no need for a blender. To fill 16 oz. water bottle: Place 2 scoops in water bottle, half fill with water, shake vigorously, and then fill to top with water.

IMPORTANT NOTICE: Improper use of this product may be hazardous to your health. Do not use if you are pregnant or nursing or are being treated for high blood pressure, heart, thyroid or psychiatric disease, diabetes, depression, seizure disorder, stroke or difficulty in urination due to prostate enlargement. Seek advice from a health care practitioner prior to use if you are taking an MAO inhibitor or any other prescription drug. Reduce or discontinue use if nervousness, tremor, sleeplessness, dizziness, headache, heart palpitations, tingling sensations, loss of appetite or nausea occur. **NOT INTENDED FOR SALE TO OR USE BY PERSONS UNDER THE AGE OF 18. KEEP OUT OF REACH OF CHILDREN.**

ATTENTION ALL ATHLETES: Anyone subject to drug-testing or doping control procedures under IOC, USOC, NCAA, IPC, or IFBB should cease using this product at least 5 days before providing urine samples.

The above statements have not been evaluated by the FDA.
This product is not intended to diagnose, cure, treat or prevent a disease.
© Next Nutrition, Inc. 1997 Not a product of The Ultimate Juice Co., New York.

99 AGO -3 AIO :04

RECEIVED
CLINICAL RESEARCH
& REVIEW/OSN HFS-430

000004

Food and Drug Administration Office of Regulatory Affairs Collection Report

For Sample Number: 59884

1 BAG RT 1303

Flag		Flag Remarks			
Episode Number	Origin	Basis	Sample Type	FIS Smpl Num	Status
	Domestic	Surveillance	Non-Regulatory	99924484	Completed
FEI	Date Collected	Product Code	Responsible Firm	PAC	Hours
3001828426	10-JUN-99	54FCR09	Manufacturer	56008B	.3
Related Smpl Num	Position Class	Sampling District	NDC Number	Permit Number	Storage Rqrmnt.
	DAP	SEA-DO			Ambient
Dealer is Consumer	Crx/DEA Schedule	Recall Num	Consumer Compl. Num	Brand Name	
Yes				Ultimate Orange	

Product Description
powdered drink mix

Product Label
paper wrap-around label

Reason for Collection	MFG Codes	Expiration Date
Analyze for ephedra alkaloids and caffeine		

Firm Legal Name	Address	Type of Firm	Firm FEI	FCE
NEXT NUTRITION	6231 YARROW DR CARLSBAD, CA 92009 US	Manufacturer	3001828426	

Size of Lot	Est. Value	Rcpt Type	Date Shipped & Doc. Ref.

Description of Sample
Ultimate Orange: 1 opened container in plastic bag with state of [redacted] seal.

Method of Collection
Received 5/26/99 by Airborne shipment from State of [redacted] Maintained in T. Savage's office until today due to FACTS downtime

How Prepared
Canister of product, in plastic bag with intact State of [redacted] seal, placed in paper bag, ID'd, and sealed.

Collector's Identification on Package and/or Label	Collector's Identification on Seal
59884, 6/10/99, TSS	59884, 6/10/99, Thomas S. Savage

Sample Delivered To	Date Delivered	Orig C/R & Records To
[redacted]	06/11/1999	SEA-DO
	Lab w/Split Sample	Lab
	0	SEA-LAB

Document Number	Document Date	Document Type	Document Remarks

Remarks
Sample received 5/26/99; maintained under State of [redacted] seal in T. Savage's office until FACTS was available for use

Payment Amount	Payment Method	704(d) Sample	702(b) Portion	Collector's Name
		No	No	Thomas S Savage
Name of Signer	Date & Time of Signature			Meaning
Thomas S Savage	06/10/1999	06:33 PM	ET	Collector
Thomas S Savage	06/10/1999	06:29 PM	ET	Collector



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Pacific Regional Laboratory NW
22201 23rd Drive S.E.
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

13418

July 16, 1999

Dear Ms. [REDACTED]

We have completed analysis of the sample of "Ultimate Orange" which you sent to us. The product was found to contain ephedrine at 20.7 mg per serving. This is 103.4% of the declared content of 20 mg per serving. It appears that there is no caffeine in the product, although the method we used for identification of caffeine was not fully conclusive due to interference from other compounds present. The analytical worksheet and related records are enclosed.

As you requested, we are sending the reserve portion of the sample to [REDACTED] of [REDACTED]

Please feel free to contact me if you have questions.

Sincerely,

Thomas S. Savage
Supervisory Chemist

RECEIVED
CLINICAL RES. & ROP
& REVIEW/OSN HFS-45
99 AGO -9 AM 1:22

Att: 59884 [REDACTED]

Cc: [REDACTED]

000006

ANALYST WORKSHEET		1. PRODUCT Ultimate Orange drink mix		2. SAMPLE NUMBER 59884	
3. SEALS <input type="checkbox"/> NONE <input checked="" type="checkbox"/> INTACT <input type="checkbox"/> BROKEN		4. DATE REC'D 6/11/99		5. RECEIVED FROM [REDACTED]	
6. DISTRICT OR LABORATORY SEA-DO					
7. DESCRIPTION OF SAMPLE One brown paper bag, officially sealed "59884 6/10/99 Thomas S. Savage", containing one plastic bag with product canister each with State of [REDACTED] seal "09849 5/21/99 [REDACTED]". Received at room temperature.					
8. NET CONTENTS <input checked="" type="checkbox"/> NOT APPLICABLE <input type="checkbox"/> NOT DETERMINED <input type="checkbox"/> UNITS EXAMINED		DECLARED/UNIT AMOUNT FOUND _____ % OF DECLARED _____		9. LABELING <input checked="" type="checkbox"/> ORIGINALS SUBMITTED <input checked="" type="checkbox"/> COPIES SUBMITTED <input type="checkbox"/> NONE	
10. SUMMARY OF ANALYSIS					
<p>container : paperboard canister, 180mm high x 102mm diameter, with translucent plastic snap on lid, ~1oz plastic scoop inside</p> <p>labeling : commercially printed paper label wrapped around canister</p> <p>code : "19913801 J06180708-56" stamped in black ink on bottom of canister</p> <p>product : pale orange powder, odor is more like vanilla than orange</p> <p>Analysis : GC/MS screen for ephedrine and caffeine results : no drugs or ephedrine alkaloids found (too much interference)</p> <p>Analysis : HPLC quantitation/ID of ephedrine by LIB 3996 results : ephedrine Rt = 9.751 sample Rt = 9.732 amount found = 20.7mg per 28.4g serving % declared = 103.4% declared (20mg per 28.4g serving declared)</p>					
RECEIVED CLINICAL RES. LAB & REVIEW/OSH HFS-6.5 99 AGO -9 AM 1:22					
000007					
11. RESERVE SAMPLE In original paper bag, officially sealed "59884 7/14/99 JL Bussey" containing one open canister, additionally id'd "59884 6/11/99 JL Bussey". Returned to sample custodian.					
12. a. ANALYST SIGNATURE (if BROKE SEAL) JL Bussey		13. WORK SHEET CHECK		a. BY Janet L. Burke	
b.				b. DATE 7-16-99	
c.		14. DATE REPORTED 14 July 99			

Sartorius A200S balance used throughout worksheet.

Analysis : GC/MS screen

instrument/parameters : see attachment A

standard prep :

25.0mg caffeine in 25.0mL methanol, diluted 1.0mL to 50.0mL (0.02mg/mL)

53.7mg ephedrine in 50.0mL methanol, diluted 1.0mL to 50.0mL (0.02mg/mL)

sample prep :

1.4g sample powder in 100.0mL methanol, sonicated 15min, 0.45µm filtered

results : see attachment A

ephedrine Rt = 9.17/9.31 (split peak)

caffeine Rt = 12.12

sample exhibits many peaks none of which correspond to standards (too much interference)

analysis : HPLC ID/quantitation of ephedrine, LIB 3996

instrument : HP1090 HPLC with YMC phenyl column, 25cm x 4.6mm x 5µm

mobile phase : 0.1M sodium acetate, 3% ACN, 8mL/L HOAc, 3mL/L TEA

parameters : 1.3mL/min, 257nm, 40°C column temperature, 25µL injection

diluting solution : mobile phase diluted 1/5 (DMP)

elution buffer : 0.15M sodium acetate, 3% ACN, 8mL/L HOAc, 3mL/L TEA

SPE columns : Isolute PRS, 500mg/6mL

internal standard stock : 250.0mg phentermine HCl in 50.0mL DMP (4.018mg/mL base)

standard prep : 76.2mg ephedrine in 25.0mL DMP, diluted 1.0mL + 2.0mL internal std sol'n to 100.0mL DMP

sample prep : 2.5059g sample powder in 50mL centrifuge tube with 1.0mL internal standard solution, dil to 25.0mL total with DMP, vortexed 2min, centrifuged 10min, 0.45µm filtered (blank IS concomitantly prepared)

SPE procedure : columns placed on vacuum manifold and washed with 2mL methanol, 2mL water and 2mL DMP.

2.0mL sample extract loaded on column and washed with two 3mL portions of DMP, then dried under vacuum for 5min.

Column then washed with 2mL 50/50 acetone/ethyl acetate and dried under vacuum for 15min. Ephedrine alkaloids eluted off SPE column with 4.0mL elution buffer. (total sample dilution : 2.5g in 50mL)

results : see attachment B

ave ephedrine Rt = 9.751min

ave sample Rt = 9.732min

000008

May 27, 1999

Thomas S. Savage
Supervisory Chemist
U.S. Food and Drug Administration
Pacific Regional Laboratory NW
22201 23rd Drive S.E.
Bothell, WA 98021-4421

Dear Mr. Savage:

We sent an official sample, one pound (almost empty) container of Ultimate Orange powder, via [REDACTED] overnight delivery, Airbill number [REDACTED], noted ARMS # 13418.

As we discussed, if there is enough of the sample, the consumer would like a portion to be shipped to their independent laboratory:

[REDACTED]

The consumer has obtained legal counsel, and they have requested the sample be sent with a legal chain of custody procedure. Copies of the the appropriate forms, upon transfer, may be sent here for forwarding to their counsel.

Thank you in advance for your cooperation in this request.

Sincerely,

[REDACTED]

[REDACTED], R.Ph.

Director

[REDACTED]

000010

RECEIPT FOR SAMPLES

SAMPLE NO.

Date: 5/21 1999 Time: 1:05 a.m. City: [REDACTED] Zip Code: [REDACTED]

Firm Name:_____

Address:

Address: [redacted] (to Date: 5/21 1999 Time: 103 a.m.)
 Delivered to: [redacted] FDA - Laboratory, Seattle Bothell, Wa. VIA Airbill# [redacted]
 Samples Collected (Describe Fully, Name of Product, Label, Manufacturer, Codes, etc.) 5/25/99 3pm. Price Paid

Price Paid

[illegible]**TOTAL PRICE PAID**

Signature of Authorized Agent

SAMPLE NO.:

000011